

### Remarks

Claims 1, 5-7, 9, 10, 13-15, 17, 18, 20 and 21 are pending in this application. Claims 2-4, 8, 11, 12, 16, 19 and 22 have been canceled. Claims 1, 5, 9, 14, 17, 18, and 20-21 are amended. Applicants request entry of the amendments and consideration of arguments presented below.

#### Rejection of claims 1, 3-15, 17, 18, 20, 21 and 23 under 35 USC §101

Claims 1, 3-15, 17, 18, 20, 21 and 23 under 35 USC §101 because the claimed invention is not considered to be supported by either a credible, specific and substantial utility or a well established utility. In addition, claims 17 and 18 are rejected under this section for being directed to non-statutory subject matter. Applicants traverse this rejection for the following reason.

The claims have been amended to now recite a utility for the organism "yeast". Moreover, by amending the claims to be directed to yeast obviates the rejection of claims 17 and 18 to non-statutory subject matter. Withdrawal of this rejection is believed to be in order and notice to that effect is respectfully requested.

#### Rejection of claims 1, 3-15, 17, 18, 20, 21 and 23 under 35 USC §112, first paragraph

Claims 1, 3-15, 17, 18, 20, 21 and 23 have been rejected under this heading for failing to comply with the written description requirement. Applicants traverse this rejection for the following reason.

All the pending claims are directed to yeast and not to multicellular organisms. As such, it is submitted that this rejection has been overcome. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of claims 1, 3-15, 17, 18, 20, 21 and 23 under 35 USC §112, first paragraph

Claims 1, 3-15, 17, 18, 20, 21 and 23 have been rejected under this heading for failing to comply with the enablement requirement. Applicants traverse this rejection for the following reason.

All the pending claims are directed to yeast and not to multicellular organisms. As such, it is submitted that this rejection has been overcome. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of claims 1, 3-17, 20 and 21 under 35 USC §112, second paragraph

Claims 1, 3 -15, 20 and 21 have been rejected under this section for being indefinite for failing to point out and distinctly claiming the subject matter Applicants regard as their invention. Applicants traverse this rejection for the following reasons.

On page 16 of the Office Action, the Examiner states that while the previous amendment on claim 1 is persuasive for the Examiner, claim 1 remains confusing because there is an alternative meaning of "phenotyping" in claim 11. In order to expedite prosecution, Applicants have canceled claim 11 to overcome this section of the rejection.

On page 17 of the Office Action, the Examiner states that the term "modified expression" in claim 5 is confusing because it can be read in two ways as being depending on step a) or step c) of claim 1. Claim 5 has been amended to recite that the term "modified expression" refers to step a) of claim 1.

Claim 12 has been canceled to expedite prosecution.

Regarding the phrase "perceptible from the outside" recited in claim 1 and dependent claims therefrom, the phrase refers to any modification or alteration of the yeast organism that can be measured on or outside of the modified organism and distinguishable from a wild-type unmodified yeast with or without the aid of an instrument. In particular the claimed invention is suitable for evaluation in HTS drug screening (see page, 2, lines 15-17, for example). On page 7, lines 13 – 17, for example, the specification sets forth that analysis can "in principle include any modifications of the mRNA or protein

steady state (transcription, translation, stabilization, etc.) and thus may also be carried out by protein profiling as well as with the aid [of] [sic] [lacuna] protein assays.”

Accordingly, both “physical” (e.g., shape, size, growth or rate of cell division, found, for example, on page 1, lines 33-38,) and “non-physical attributes” such as secreted proteins that are recovered and tested are encompassed by the specification and the term “perceptible from the outside” of the yeast organism. The metes and bounds of the phrase are implied throughout various sections of the application.

Accordingly, it is believed that this rejection has been overcome and notice to that effect is respectfully requested.

Rejections under 35 §USC 102(b)

Claims 1, 3-5 8-11, 17, 18, 20, 21 and 23 are rejected under 35 §USC 102(b) as being anticipated by Chattopadhyay et al. Applicants traverse the rejection.

Applicants have amended claim 1 and dependent claims therefrom such that the heterologous expression of at least one protein or protein fragment occurs as a result of introducing a foreign gene into the yeast organism. Support for said amendment may be found, for example, on page 4, line 27 of the instant specification.

Chattopadhyay teaches that yeast strain carrying a deletion of the endogenous gene BTN1 compensated for the altered plasma membrane H<sup>+</sup> -ATPase activity by elevating the expression of the HSP30 and BTN genes. Deletion of all three genes caused poor growth at low pH in a medium containing sorbic acid.

Applicants submit that in light of the instant amendment, Chattopadhyay et al. does not anticipate the claimed invention and that this rejection has been overcome.

Should the Examiner believe that an interview would advance the prosecution of this application, the Applicants invite him to contact the undersigned at 908.231.4658.

Respectfully submitted,



---

Karen I. Krupen, Reg. No. 34,647  
Attorney for Applicants

sanofi-aventis U.S. Inc  
Patent Department  
Route #202-206 / P.O. Box 6800  
Bridgewater, NJ 08807-0800  
Telephone (908) 231-4658  
Telefax (908) 231-2626  
Docket No. DEAV2002/0089 US NP